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Attorney Docket No.: MDSP-P04-180

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:			
	Shaughnessy *et al.*	Attorney Docket No.	MDSP-P04-180
Serial No:	10/779,890	Art Unit:	1646
Filed:	February 17, 2004	Examiner:	KEMMERER, E.
For:	Osteoporosis Treatment		

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SECOND PRELIMINARY AMENDMENT

Sir:

Please enter the following amendments:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (**Original**) A process of increasing bone density in a mammalian patient suffering from a pathological condition in which bone density is decreased which comprises inhibiting the formation of a tertiary complex of IL-11, IL-11R, and gp130.

2. (**Original**) The process of claim 1 which comprises administering to the patient an effective amount of a substance which inhibits, *in vivo*, the formation of a tertiary complex of IL-11, IL-11R, and gp130.

3. (**Currently Amended**) The process of claim 2 wherein the pathological condition is selected from the group consisting of: osteoporosis, metastatic bone cancer, myeloma, Paget's disease, and bone fracture ~~postmenopausal bone loss~~.

4. (**Original**) The process of claim 2 wherein the substance is a mutant IL-11R.

5. (**Original**) The process of claim 4 wherein the substance is a mutant IL-11R with at least one mutation in its gp130 binding region.

6. (**Original**) The process of claim 5 wherein the substance is a mutant IL-11R having at least one of the following mutations: D282 → G282, A283 → D283, G286 → D286, H289 → Y289, and V291 → L291.

7. (**Original**) The process of claim 6 wherein the substance is a mutant IL-11R having the mutation H289 → Y289.

8. (**Original**) The process of claim 4, wherein the substance is a soluble mutant IL-11R.

9. (**Original**) The process of claim 8 wherein the mutant IL-11R is a human IL-11R.

10. (**Original**) The process of claim 2 wherein the substance is an anti IL-11 antibody.

11. (**Original**) The process of claim 2 wherein the substance is an IL-11 binding peptide.

12. **(Original)** The process of claim 11 wherein the substance is an IL-11 binding peptide having an amino acid sequence which specifically binds IL-11 in the region normally bound by IL-11R.

13. **(Original)** The process of claim 12 wherein the substance is a peptide comprising the sequence Arg Arg Leu Arg Ala Ser Trp.

14. **(Original)** The process of claim 2 wherein the substance is a small molecule.

15. **(Original)** The process of claim 2 wherein the substance is an IL-11 antagonist.

16. **(Original)** The process of claim 2 wherein the substance is an IL-11R binding peptide.

17. **(Original)** The process of claim 2 wherein the substance is an anti IL-11R antibody which inhibits interactions between IL-11 and the IL-11R.

18. **(Original)** The process of claim 2 wherein the substance is an anti IL-11R antibody which inhibits interactions between IL-11R and gp130.

19. **(Original)** The process of claim 2 wherein the substance is an effective amount of transcribable genetic material which causes inhibition of the formation of the tertiary complex of IL-11, IL-11R, and gp130.

20. **(Original)** The process of claim 19 wherein the transcribable genetic material encodes an RNA sequence capable of inhibiting the translation of a component necessary to the formation of the IL-11 / IL-11R / gp130 tertiary complex.

21. **(Original)** The process of claim 20 wherein the transcribable genetic material comprises DNA encoding an RNA sequence complementary to IL-11 mRNA.

22. **(Original)** The process of claim 20 wherein the transcribable genetic material comprises DNA encoding an RNA sequence complementary to IL-11R mRNA.

23. **(Original)** The process of claim 20 wherein the transcribable genetic material comprises DNA encoding an RNA sequence complementary to gp130 mRNA.

24. **(Original)** The process of claim 19 wherein the transcribable genetic material comprises DNA encoding an amino acid sequence capable of inhibiting the formation of the IL-11 / IL-11R, gp130 tertiary complex.

25. **(Original)** The process of claim 24 wherein the transcribable genetic material encodes an IL-11R mutated to inhibit binding to gp130.

26. **(Original)** The process of claim 24 wherein the transcribable genetic material encodes an IL-11 binding peptide.

27. **(Original)** The process of claim 19, wherein the level of transcription of the transcribable genetic material is dependant on the concentration of an inducing compound.

28. **(Original)** The process of claim 1, in which the patient is a human.

29-33. **(Canceled)**

34. **(Original)** A composition of matter comprising an IL-11 binding peptide.

35. **(Original)** The composition of claim 34 wherein the IL-11 binding peptide comprises the sequence Arg Arg Leu Arg Ala Ser Trp.

36. **(Original)** The composition of claim 34 wherein the IL-11 binding peptide comprises the sequence Arg Arg Leu His Ala Ser Trp.

37. **(Original)** The composition of claim 34 wherein the IL-11 binding peptide comprises the sequence Arg Arg Leu X Ala Ser Trp, and X is a basic amino acid.

38. **(Original)** The composition of claim 34 wherein the IL-11 binding peptide comprises the sequence Ser Ile Leu Arg Pro Asp Pro Pro GIn Gly Leu Arg Val Glu Ser Val Pro Gly Tyr Pro.

39. **(Original)** The composition of claim 34 wherein the IL-11 binding peptide comprises the sequence Ser Ile Leu Arg Pro Asp Pro Pro Gln Gly Leu Arg Val Glu Ser Val Pro Ser Tyr Pro.

40. **(Original)** Use of the peptide of claims 34 in reducing the formation of a tertiary complex of IL-11, IL-11R and gp130.

41. **(Original)** Use of the peptide of claim 34 in the purification of IL-11.

42. **(Original)** Use of the peptide of claim 34 in the depletion of IL-11 from a solution.

43. **(Original)** A composition of matter for the selective binding of IL-11 comprising the peptide of claim 34 suitably immobilized on an appropriate substrate.

44. **(Original)** A composition of matter comprising an IL-11R binding peptide.

45. **(Original)** Use of an antibody which specifically bins the IL-11R and blocks interactions between IL-11 and IL-11R in the preparation of a medicament for use in increasing bone density in a mammalian patient.

46. **(Original)** Use of an antibody which specifically bins the IL-11R and blocks interactions between gp130 and IL-11R in the preparation of a medicament for use in increasing bone density in a mammalian patient.

47. **(Original)** The use of the TRAP assay in identifying IL-11 antagonists.

48. **(Original)** The use of the bone marrow formation assay in identifying IL-11 antagonists.

49. **(Original)** A process of increasing bone formation while decreasing bone resorption in a mammalian patient, which comprises inhibiting the formation of a tertiary complex of IL-11, IL-11R and gp130.

REMARKS

Upon entry of this amendment, claims 1-28 and 34-49 constitute the pending claims in the present application.

Applicants have amended Claim 3 to clarify the subject matter claimed. Support can be found throughout the specification. *See*, for example, paragraphs [0004] and [0016] in the published patent application **US 2004-0142871 A1**.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**, under **MDSP-P04-180**.

Respectfully Submitted,

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